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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-0199]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Importation of Etiologic Agents (42 CFR 71.54) (OMB Control No. 0920-0199, exp. 1/31/2014) - Revision - Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes the Secretary of Health and Human Services to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F - Importations - contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC.

CDC requests Office of Management and Budget approval to collect information for three years using the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States and Application for a Permit to Import or Transport Live Bats. We are also requesting a title change to read -- *Import Permit Applications* (42 CFR 71.54).

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. CDC plans to revise this application to request information on where the imported material will be stored at the recipient facility and who would be responsible for this location; verification that the permittee has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use; and a secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will not affect the burden hours.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition or scientific purposes to request a

permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC plans to revise this application to request secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will not affect the burden hours.

Estimates of burden for the survey are based on information obtained from the CDC import permit database based on the number of permits issued on annual basis since 2010. The total estimated annual burden for the data collection is 545 hours. We estimate a decrease in the number of respondents from 2,000 in 2011 to 1,625 due to recent trends and changes in the regulation. The daily operations have observed a decrease in the number of request for an import permit since 2011. In addition, the changes in 42 CFR 71.54, which became effective April 5, 2013, specify situations where an application for a permit is no longer required. For example, the importation of a select agent that is regulated under 42 CFR Part 73 no longer requires a permit be issued.

There are no costs to respondents except their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Infectious Biological Agents into the United States	1,625	1	20/60
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats	10	1	20/60

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